

REMARKS/ARGUMENTS

Claims 53, 58-72, 74, and 77-97 are pending in the current application.

Rejection under 35 U.S.C. § 112, first paragraph: enablement

Claims 53, 58-73, and 77-97 were rejected as allegedly lacking enablement. The Examiner states that the claims are enabled form methods comprising administration of full length SEQ ID NO:2, but are not enabling for the administration of fragments of SEQ ID NO:2. Applicants respectfully traverse.

As identified in the Patent Office and the Federal Circuit, whether undue experimentation is required by one skilled in the art to practice to invention is determined by considering factors such as the amount of guidance presented in the application, the state of the prior art, and the presence of working examples. *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1985); *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). As described in *Wands*, a “considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should precede.” *Wands*, 8 USPQ2d at 1404 (quoting *In re Jackson*, 217 USPQ 804 (Bd. Pat. App. & Int. 1982).

The Examiner states that fragments of PSCA are not enabled, as administering a fragment of a protein is unpredictable in its ability to induce an immune response. In order to expedite prosecution, Applicants have amended the claims to recite “immunogenic fragments” of SEQ ID NO:2. This amendment adds no new matter. Support for this amendment can be found in the specification, e.g., page 30, lines 20-21. This amendment addresses any concerns that the Examiner has raised regarding inoperable embodiments, as the claims now require that the PSCA fragments are immunogenic.

Applicants have also amended the claims to recite specific cancers for therapeutic treatment (prostate, prostates metastases, bladder cancer, and pancreatic cancer) and to recite that the cancers overexpress PSCA. This amendment adds no new matter. Support for this amendment can be found, e.g., in the specification on page 19, lines 7-10. The specification describes PSCA as an optimal therapeutic target, due to its cell surface location, as well as

providing evidence that PSCA protein is overexpressed in prostate cancer cells (Figures 9-11), prostate cancer metastases to bone (Figures 20-24 and 26-32, bladder carcinomas (Figures 6, 25, and 62), and pancreatic carcinomas (Figures 63 and 64) (see also page 5, lines 14-15 and page 19, lines 7-10). This overexpression correlates with increasing grade of the cancer and poor prognosis (page 19, lines 10-13). The data provided in the specification therefore demonstrates that the named cancers are targets for PSCA therapy.

The specification further provides assays for identifying immunogenic peptides (*see, e.g.*, page 30, lines 17-26; and page 60, lines 27-29), as well as assays for making and administering such immunogenic peptides (*see, e.g.*, page 22, line 26 to page 23, line 2; page 31, lines 13-20; page 58, line 30 to page 59, line 25; page 60, lines 9-30; and page 61, lines 1-16). Furthermore, such methods are well known to those of skill in the art. Finally, the specification provides working examples of a PSCA fragment used to raise an immune response (*see, e.g.*, Example 18). One of skill in the art, given the assays and data disclosed in the specification, as well as the information known in the art, would have to practice only routine experimentation to identify and use immunogenic peptides of the invention. Applicants respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 103

The Examiner rejected claims 53, 74, 77-81, and 97 as allegedly obvious over Au-Young in view of Spitler. Applicants respectfully traverse.

Applicants first note that the Examiner appears to believe that the combination of Au-Young and Spitler are enabling references that would motivate one of skill in the art to practice the claimed invention. As such, Applicants believe that either the enablement rejection, or the obviousness rejection is improper. If both Au-Young and Spitler are enabling, then Applicant's invention is also enabled. Conversely, if the present invention is not enabled, then neither is the combination of Au-Young and Spitler. Applicants therefore request that the Examiner withdraw either the enablement or the obviousness rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art references must teach or suggest all the claim limitations; second, there must be

some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to combine the limitations; third, there must be a reasonable expectation of success in combining the limitations. MPEP §2143. Furthermore, it is well recognized that an obviousness rejection requires a particularized teaching or suggestion to combine the elements to make the claimed invention. *See In re Mills*, 16 USPQ 2d 1430 (Fed. Cir. 1990); *see also In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992).

As described above, Applicants have also amended the claims to recite specific cancers for therapeutic treatment (prostate cancer, prostates metastases, bladder cancer, and pancreatic cancer) and to recite that the cancers overexpress PSCA. The cited references thus fail to teach or disclose that one of skill in the art could treat specific cancers that overexpress PSCA protein. Neither Au-Young nor Spitler teach that PSCA protein is overexpressed in prostate cancer, prostates metastases, bladder cancer, or pancreatic cancer. Although Au-Young discloses that PSCA nucleic acids are expressed in both normal bladder and bladder tumors, one of skill in the art would not reasonably expect that PSCA protein is overexpressed in bladder cancer, thereby making such cancers a target for PSCA therapy. As the cited references fail in combination to teach or suggest the claimed invention, Applicants request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 78 was rejected as allegedly indefinite for failing to specify in the preamble the antigen to which the immune response is being raised. Applicants have amended the claims to recite that the immune response is directed against PSCA. Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 09/854,811


PATENT

Amdt. dated April 16, 2004

Reply to Office Action of October 16, 2003

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Annette S. Parent". The signature is fluid and cursive, with the first name "Annette" being more prominent.

Annette S. Parent

Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP

Two Embarcadero Center, Eighth Floor

San Francisco, California 94111-3834

Tel: 415-576-0200

Fax: 415-576-0300

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